BIOCHEMISTRY PAIN RELIEF FOOT ACTIVE- benzyl alcohol, lidocaine hydrochloride liquid Pure Source, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

biochemistry PAIN RELIEF FOOT SPRAY ACTIVE

biochemistry PAIN RELIEF FOOT SPRAY ACTIVE

Active ingredients

Benzyl Alcohol 19% Lidocaline HCL 4%

Purpose

Topical Anesthetic

Uses

• For temporary relief of minor foot pain.

Warnings

For external use only

•

Avoid contact with eyes

- Do not apply to open wounds or damaged skin
- If pain persists consult a physician. If conditions worsens, or if symptoms persist for more than seven days, or if conditions clear up and occur again within a few days, discontinue use of this product and consult a physician

Do not use

in large quantities over raw surfaces or blistered areas

Consult your doctor

if any adverse effect or allergy develops

If pregnant or breast-feeding

ask a health professional before use

Keep out of reach of children

• If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Over 12-years
- Apply directly to affected area

- Do not wrap affected area
- Do not use more than four times per day

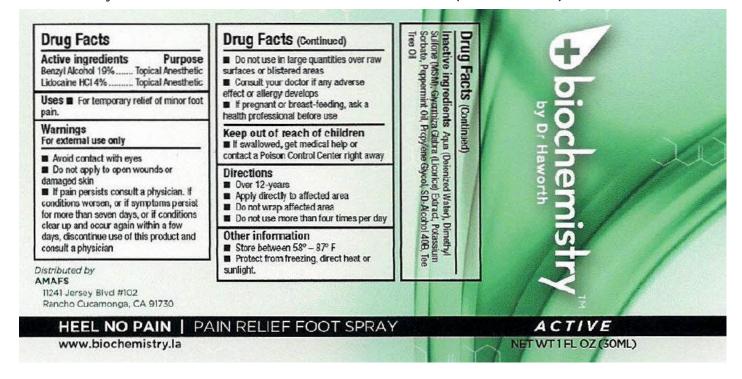
Other information

- Store between 58 ° 87 ° F
- Protect from freezing, direct hear or sunlight.

Inactive ingredients

Aqua (Deionized Water), Dimethyl Sulfone (MSM), Glycyrrhiza Glabra (Licorice) Extract, Potassium Sorbate, Peppermint Oil, Propylene Glycol, SD-Alcohol 40B, Tea Tree Oil

biochemistry PAIN RELIEF FOOT SPRAY ACTIVE 30ml (65121-209-31) | biochemistry PAIN RELIEF FOOT SPRAY ACTIVE 60ml (65121-209-32)



Drug Facts Active ingredients Purpose Benzyl Alcohol 19% Topical Anesthetic Lidocaine HCI 4% .. . Topical Anesthetic Uses ■ For temporary relief of minor foot Easy To Apply pain. **Spray Bottle** Warnings For external use only Non-Greasy Avoid contact with eyes Do not apply to open wounds or **Effective Pain** damaged skin Relief For: ■ If pain persists consult a physician. If by Dr Hawort conditions worsen, or if symptoms persist for more than seven days, or if conditions Ankles clear up and occur again within a few days, discontinue use of this product and · Arches consult a physician Do not use in large quantities over raw · Balls Of Feet surfaces or blistered areas ■ Consult your doctor if any adverse · Heels effect or allergy develops If pregnant or breast-feeding, ask a · Toes health professional before use Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away Directions ■ Over 12-years ■ Apply directly to affected area Do not wrap affected area Do not use more than four times per day Other information ■ Store between 58° - 87° F ■ Protect from freezing, direct heat or Inactive ingredients Aqua (Delonized Water), Dimethyl Sulfone (MSM), Glycrrhiza Glabra (Licorice) Extract, Potassium Sorbate, Peppermint Oil, Propylene Glycol, SD-Alcohol 40B, Tee Tree Oil Pain Relief Foot Spray www.biochemistry.la

11241 Jersey Blvd #102 Rancho Cucamonga, CA 91730

Made in USA @ 2013

ACTIVE

NET WT1FL OZ (30ML)

Drug Facts

Active ingredients Purpose Benzyl Alcohol 19% Topical Anesthetic Lidocaine HCI 4% Topical Anesthetic

Uses ■ For temporary relief of minor foot pain.

Warnings For external use only

- Avoid contact with eyes
- Do not apply to open wounds or damaged skin
- If pain persists consult a physician. If conditions worsen, or if symptoms persist for more than seven days, or if conditions clear up and occur again within a few days, discontinue use of this product and consult a physician

Distributed by AMAFS

> 11241 Jersey Blvd #102 Rancho Cucamonga, CA 91730

Drug Facts (Continued)

- Do not use in large quantities over raw surfaces or blistered areas
- Consult your doctor if any adverse effect or allergy develops
- If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Over 12-years
- Apply directly to affected area
- Do not wrap affected area
- Do not use more than four times per day.

Other information

- Store between 58° 87° F
- Protect from freezing, direct heat or

Drug Facts

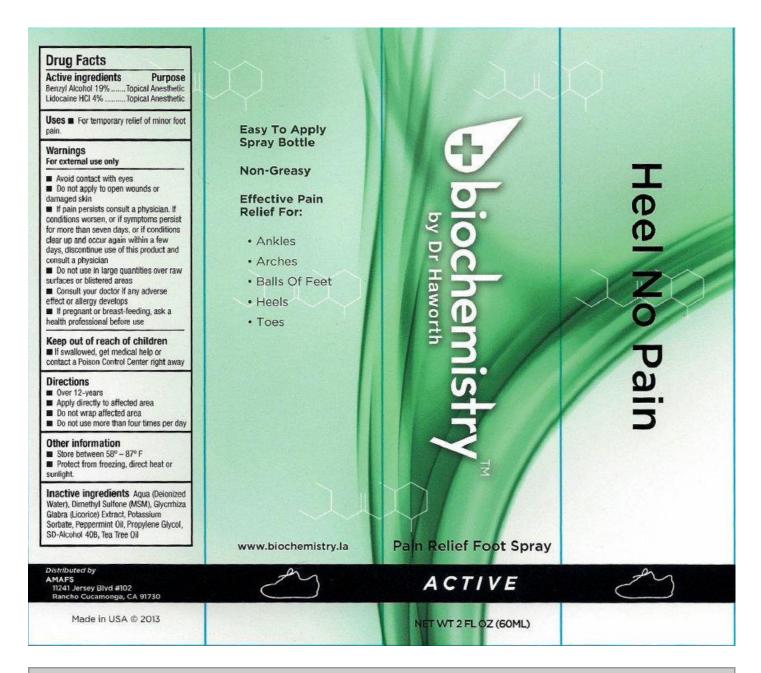
Inactive ingredients Aqua (Delonized Water), Dimethyl Sulfone (MSM), Glycrhiza Glabra (Licorice) Extract, Potassium Sorbate, Peppermint Oil, Propylene Glycol, SD-Alcohol 40B, Tee (Continued)

PAIN RELIEF FOOT SPRAY HEEL NO PAIN

ACTIVE

www.biochemistry.la

NET WT 2 FL OZ (60ML)



BIOCHEMISTRY PAIN RELIEF FOOT ACTIVE

benzyl alcohol, lidocaine hydrochloride liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65121-209	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH) (BENZYL ALCOHOL - UNII:LKG8494WBH)	BENZYL ALCOHOL	190 mg in 1 mL	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98 PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)			
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			
PEPPERMINT OIL (UNII: AV092KU4JH)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
TEA TREE OIL (UNII: VIF565UC2G)			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:65121-209- 31	1 in 1 CARTON	02/09/2017		
1		30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product			
2	NDC:65121-209- 32	1 in 1 CARTON	02/09/2017		
2		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/06/2014	

Labeler - Pure Source, LLC (080354456)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pure Source, LLC		080354456	manufacture(65121-209), repack(65121-209), relabel(65121-209)	

Revised: 2/2017 Pure Source, LLC